for a hearing on proposals to refuse approval or to withdraw approval of new drug applications and abbreviated new drug applications and supplements thereto on drugs for human use that have been submitted under section 505 of the act and subpart B of part 314 of this chapter and to issue notices refusing approval or withdrawing approval when opportunity for hearing has been waived.

(c) These officials may not further redelegate these authorities.

§ 5.106 Submission of and effective approval dates for abbreviated new drug applications and certain new drug applications.

(a) The following officials are authorized to perform all of the functions of the Commissioner of Food and Drugs with regard to decisions made under section 505 (c)(3)(D), (j)(4)(B)(iv), and (j)(4)(D) and section 505A of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(c)(3)(D), (j)(4)(B)(ii) and (j)(4)(D) and 355a) concerning the date of submission or the date of effective approval of abbreviated new drug applications including supplements thereto submitted under section 505(j) of the act (21 U.S.C. 355(j)) and of new drug applications including supplements thereto submitted under section 505(b)(1) (21 U.S.C. 355 (b)(1)) of the act and described under section 505(b)(2) of the act (21 U.S.C. 355(b)(2)):

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Generic Drugs, Office of Pharmaceutical Science, CDER.

(b) These officials may not further redelegate this authority.

§ 5.107 Extensions or stays of effective dates for compliance with certain labeling requirements for human prescription drugs.

(a) The following officials are authorized to extend or stay an effective date in § 201.59 of this chapter for compliance with certain labeling requirements for human prescription drugs.

(1) For drugs assigned to their organizations:

(i) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER).

(ii) The Directors and Deputy Directors, Office of Blood Research and Review (OBRR), Office of Vaccines Research and Review (OVRR), and Office of Therapeutics Research and Review (OTRR), CBER.

(iii) The Directors and Deputy Directors of the Divisions in OBRR, OVRR, and OTRR, CBER.

(2) For drugs assigned to their organizations:

(i) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(ii) The Directors and Deputy Directors of the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(iii) The Directors and Deputy Directors of the divisions in the Offices of Drug Evaluation I, II, III, IV, and V, Office of Review Management, CDER.

(b) These officials may not further redelegate this authority.

§ 5.108 Authority relating to waivers or reductions of prescription drug user fees.

The Director, Center for Drug Evaluation and Research (CDER), and the Associate Director for Regulatory Policy, CDER, are authorized to perform all the functions of the Commissioner of Food and Drugs relating to waivers or reductions of prescription drug user fees under the Prescription Drug User Fee Act of 1992, as originally enacted and as reauthorized by the Food and Drug Administration Modernization Act of 1997, except for the functions under section 736(d)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379h(d)(1)(C)) that pertain to situations where ''the fees will exceed the anticipated present and future costs,'' on behalf of CDER, the Center for Biologics Evaluation and Research, and any other Food and Drug Administration Center. This authority pertains to waivers requested under the public health waiver provision (21 U.S.C. 379h(d)(1)(A)); the barrier to innovation waiver provision (21 U.S.C.

379h(d)(1)(B)); the applications submitted under section 505(b)(1) and (b)(2) of the Federal Food, Drug, and Cosmetic Act waiver provision (21 U.S.C. 379h(d)(1)(D)); the small business waiver provision (21 U.S.C. 379h(d)(1)(E)); and to requests for refunds of fees if an application or supplement is withdrawn after filing (21 U.S.C. 379h(a)(1)(G)); as well as waivers, reductions, or refunds requested on any other basis except fees exceeding the cost. (See § 5.20(h)(1) for the authority to reconsider any user fee decisions made by the Chief Mediator and Ombudsman, the Deputy Chief Mediator and Ombudsman, and/or the former Deputy User Fee Waiver Officer prior to July 1, 1999.) These officials may not further redelegate this authority.

§ 5.109 Issuance of written notices concerning patent information, current good manufacturing practices and false or misleading labeling of new drugs.

(a) The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs under § 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) regarding the issuance of written notices.

(1) The Director, the Deputy Director, and the Directors, Office of Review Management and Office of Pharmaceutical Science, Center for Drug Evaluation and Research (CDER).

(2) The Director and Deputy Director, Office of Compliance, CDER.

(3) The Director and Deputy Director, Division of Labeling and Nonprescription Drug Compliance, Office of Compliance, CDER.

(4) The Director and Deputy Director, Division of Manufacturing and Product Quality, Office of Compliance, CDER.

(5) The Director and Deputy Director, Division of Prescription Drug Compliance and Surveillance, Office of Compliance, CDER.

(6) The Associate Director for Medical Policy, and the Director and Deputy Director, Division of Scientific Investigations, Office of Medical Policy, CDER.

(7) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER), the Director and Deputy Directors, Office of Compliance and Biologics Quality (OCBQ), CBER, and the Directors, Division of Case Management, Division of Inspections and Surveillance, and Division of Manufacturing and Product Quality, OCBQ, CBER.

(8) The Director and Deputy Directors for Science and for Regulations and Policy, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors of the Office of Device Evaluation, CDRH.

(9) Regional Food and Drug Directors.

(10) District Directors.

(b) These officials may not further redelegate this authority.

Subpart D—Biologics; Redelegations of Authority

§ 5.200 Functions pertaining to safer vaccines.

(a) The Director and Deputy Directors, Center for Biologics Evaluation and Research (CBER) are authorized to perform the functions of the Commissioner of Food and Drugs (Commissioner) under part C, subtitle 2 of title XXI of the PHS Act (42 U.S.C. 300aa–25 *et seq.*), as amended, and the National Childhood Vaccine Injury Act of 1986 (42 U.S.C. 300aa–1 note), as amended hereafter, as follows:

(1) Section 2125 of the PHS Act (42 U.S.C. 300aa–25)–Recording and reporting of information.

(2) Section 2127 of the PHS Act (42 U.S.C. 300aa–27)–Mandate for safer childhood vaccines.

(3) Section 2128 of the PHS Act (42 U.S.C. 300aa–28)–Manufacturer recordkeeping and reporting.

(4) Section 312 of the National Childhood Vaccine Injury Act of 1986–Related studies (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the review of vaccines and related illnesses and conditions under sections 312(a) and (d) of the National Childhood Vaccine Injury Act of 1986 is not redelegated by the Commissioner.

(5) Section 313 of the National Childhood Vaccine Injury Act of 1986–Study of other vaccine risks (42 U.S.C. 300aa–1 note), except that the authority to provide for notice and opportunity for public hearing on the establishment of